CG Bio Co., Ltd.

510(k) SUMMARY

1. Submitter Information

Sponsor

Name:	CG Bio Co., Ltd.
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US Agent

NOV 1 3 2013

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Official Correspondent

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	Regulatory Affairs
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2. Subject Device Information

Type of 510(k) submission:	Traditional
Trade Name:	KulaVAC
Common/Usual Name:	Foam Dressing
Classification Name:	Accessory to Powered Suction Pump
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Regulation Class:	Class II
Panel:	General & Plastic Surgery

3. Predicate Device Information

Sponsor	K.C.I	Smith & Nephew, Inc.
Device Name	V.A.C.® GranuFoam® Dressing	Renasys™-F NPWT Foam Dressing
510(k) Number	K032310	K082211
Product Code	OMP	OMP
Regulation No.	21 CFR 878.4780	21 CFR 878.4780
Regulation Class	II	II

4. Device Description

KulaVAC is wound dressing kit for Negative Pressure Wound Therapy (NPWT). The kit consists of individually reviewed medical components; polyurethane foam wound dressing, suction head, tubing, connectors, clamps and acrylic adhesive transparent film.

Foam dressing is available in three sizes; small, medium and large, and the other accessories are used to connect to a suction device.

The kit is supplied sterile and is single-use.

5. Indications for Use

KulaVAC Foam Dressing Kit is intended to be used in conjunction with suction devices to deliver negative pressure wound therapy to the wound. KulaVAC Foam Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material, and tissue debris. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

6. Non-Clinical Testing

Non-clinical testing was performed to assess the safety and effectiveness of KulaVAC. The non-clinical tests included bench testing using a mock wound model to verify the substantial equivalence to the predicate device in performance, wound dressing test in accordance with EN 13726-1 and biocompatibility testing in accordance with ISO 10993-1, respectably. And the compatibility of the device with the vacuum sources was demonstrated. All tests conducted for KulaVAC had successfully met the acceptance criteria, which demonstrate the safety and effectiveness of the device.

7. Comparison to Predicate Device

KulaVAC Foam Dressing Kit is substantially equivalent in design, materials, technology, function and intended use to its predicate devices. The minor technological differences between KulaVAC and its predicate devices raise no new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Devices		Verdict
Product Name	KulaVAC	V.A.C.® GranuFoam® Dressing	Renasys™-F NPWT Foam Dressing	-
510(k) Number	Applying	K032310	K032310	-
Product Code	OMP	OMP	OMP	SE
Regulation No.	21 CFR 878.4780	21 CFR 878.4780	21 CFR 878.4780	SE
Materials	- Foam Dressing : Polyurethane - Film Dressing : Acrylic adhesive polyurethane film			SE
Components	Composed of foam, tubing and adhesive film			SE
Intended Use	Combination with a suction device to deliver negative pressure to the wound to promote wound healing by drainage of fluids and infectious materials			SE
Indications	Chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.			SE

8. Conclusion

KulaVAC Foam Dressing Kit is substantially equivalent in design, materials, technology, function and intended use to its predicate devices. The minor technological differences between KulaVAC and its predicate devices raise no new issues of safety or effectiveness.

Performance data demonstrate that KulaVAC is as safe and effective as its predicate device, and comparable to the various controlled suction devices.

Thus, KulaVAC is substantially equivalent.

9. Summary Prepared Date

18 October 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 13, 2013

CGBio Co., Ltd.
% JungEun Im
223-23 Sangdaewon-dong, Jungwon-gu,
Seongnam, Gyeonggi-do,
462-120, Korea

Re: K122490
Trade/Device Name: KulaVAC Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 18, 2013
Received: October 29, 2013

Dear JungEun Im:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122490

Device Name: KulaVAC

Indications for Use:

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Prescription Use ___√___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S
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